IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

LAC DU FLAMBEAU BAND OF
LAKE SUPERIOR CHIPPEWA INDIANS

Plaintiff,

v.

Case No.: 18-CV-228

MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; CVS HEALTH CORPORATION; WALGREENS BOOTS ALLIANCE, INC.; WAL-MART STORES, INC.; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT, PLC d/b/a MALLINCKRODT PHARMACEUTICALS, JOHN DOES 1 THROUGH 100, INCLUSIVE,

COMPLAINT

JURY TRIAL DEMANDED

Defendants.

COMPLAINT

Plaintiff, LAC DU FLAMBEAU BAND OF LAKE SUPERIOR CHIPPEWA INDIANS, complains and alleges against each and every Defendant, and their agents, as follows:

1. An epidemic of prescription opioid abuse is devastating the adults, children, babies, institutions, and resources of Indian Country, in particular causing the LAC DU FLAMBEAU BAND OF LAKE SUPERIOR CHIPPEWA INDIANS (hereinafter "Lac Du Flambeau" or "Tribe") substantial loss of resources, economic damages, addiction, disability, and harm to the health and welfare of the Tribe, Tribal Members, non-Tribal Member inhabitants of the Tribe's Indian Lands (such as Tribal member spouses and descendants) and employees of the Tribe and/or wholly-owned enterprises of the Tribe.

2. The Defendants have engaged in a lengthy civil conspiracy, via fraud, misrepresentation, and intentional wrongful conduct, to cause as many people as possible to use and get addicted to opioid prescription pills in a maddened drive to profit billions of dollars and in a reckless disregard of the consequences to the American and Native American people.

3. The prescription opioids epidemic has been building for years and is a current and ongoing nuisance on the property and to the lives of Lac Du Flambeau. The Tribe lacks the financial resources to adequately abate the epidemic. This epic epidemic, the worst public health crisis in the 21st Century, has been intentionally concealed, minimized, denigrated, defended, and otherwise misrepresented by the Defendants and their agents, all of who have been fueling the epidemic in order to generate billions of dollars in profits, to the detriment of the Tribe and the lives of its Members, including innocent, defenseless babies born addicted to opioids.

4. In the Tribe, as everywhere in the United States, prescription opioids are more addictive than any other substance, and deadlier and more devastating than any prescription or non-prescription drug, including heroin. The devastation to the Tribe is pervasive. Child welfare costs associated with opioid-addicted parents have skyrocketed. The Tribe's medical costs are overwhelming due to the costs of the opioid epidemic. Foster care costs have substantially increased. Education and addiction therapy costs have multiplied. The Tribe has suffered economic losses from the treatment and care of babies who are born addicted to opioids. The Tribe's health and welfare fund has been imperiled and significantly depleted due to the opioid crisis. It is no wonder that in 2016, the U.S. Surgeon General, in a bit of an understatement, declared that the "prescription opioid epidemic that is sweeping across the U.S. has hit Indian country particularly hard."

5. Lac Du Flambeau provides medical services and treatments for opioid-related injuries and addiction through tribal clinics and treatment centers. These clinics and treatment centers are financially burdened with the costs associated with treating opioid-related injuries. The Tribe maintains an addiction clinic that incorporates Tribal traditions and values and services 20 beds.

6. Native Americans are at least two times more susceptible to opioid addiction than the rest of the U.S. population at large. Native American high school students are two to three times more prone to try opioid pills than U.S. teenagers in general. Native Americans are three (3) times more likely to die from a drug overdose than the rest of the U.S. population. Native American Country is usually located in more rural parts of the U.S., where medically assisted addiction treatment is unavailable, underfunded, or overwhelmed by demand. Often, Native Americans cannot even find opioid addiction treatment within reasonably proximity.

Members of Lac Du Flambeau who require opioid addiction treatment are forced to travel over 80 miles on a daily basis to find treatment.

7. Prescription opioids killed over **40,000** Americans in 2017. Prescription opioids kill twice as many people in the U.S. as heroin. Prescription opioids and related drug overdose deaths exceed the number of car accident deaths in the United States. Nearly 150 Americans die every day from opioid overdoses. Almost 91% of persons who have a non-fatal overdose of opioids are prescribed opioids again within one year. **The opioid epidemic has tragically claimed the lives of numerous Lac Du Flambeau members. Approximately 100 members of the Tribe have overdosed on opioids.**

8. **One third (1/3) of all children who go into foster parent care do so because of the opioid addiction of their parent(s).** Seven (7) in ten (10) opioid overdoses that are treated in an emergency room due to abuse of prescription opioids. **An opioid-addicted baby is born every thirty (30) minutes in America. Approximately 60 percent of the Tribe's annual births result in opioid-addicted babies. In 2017 alone, 48 of the Tribe's 80 births resulted in opioid-addicted babies.**

9. The Tribe maintains its own police force, which is the only law enforcement entity dealing with the opioid epidemic on the Tribe's reservation. It has incurred substantial costs in an effort to contain and minimize the devastating effects that the opioid crisis had had on the Tribe's lands.

10. Tribes and Native Americans have been left out of major initiatives by state governments, municipal governments, and county governments and the federal government in attempts to remedy the opioid crisis.

11. While prescription opioid use has decreased slightly in the U.S. in the past two years, deaths have continued to rise. The great nuisance created by the Defendants remains unabated and is not likely to be abated except via civil litigation.

12. This epidemic and its consequences could have been, and should have been, prevented by the opioid delivery industry created by the Defendants, especially the distribution network that controls delivery to consumers of opioid prescription drugs, which often times end up in illegal, black markets of prescription opioid drugs through what is called opioid diversion. Instead of acting with reasonable care and in a truthful manner, the Defendants, in reckless disregard for the consequences, increased prescription opioid distribution and flooded Lac Du Flambeau and other federally recognized Indian and Alaskan Native tribal communities with prescription opioids. These facts and others as alleged in this Complaint have only recently come to light, despite Defendants' efforts to conceal the truth.

13. The prescription drug distribution industry is supposed to serve as a "check and balance" in the drug delivery system, by securing opioids in the distribution chain and through the monitoring of opioid orders and sales at every step in the stream of commerce. The drug distribution industry has a duty to prevent opioids from illicit distribution, theft, misuse, diversion, and over-prescription. Pursuant to federal and state laws, drug distributors are required to report "red flags," which include suspicious or unusual orders from downstream pharmacies, doctors, clinics, or other third parties. Defendants woefully failed in these duties, instead consciously ignoring known or knowable problems and data in their supply chains.

14. Each Defendant, individually and in conspiracy with all or some of the other Defendants, intentionally and/or negligently created a drug delivery system in which vast amounts of opioids flowed freely from drug manufacturers to innocent patients who became

addicted, to babies in pregnant mothers, to opioid abusers, and even to illicit drug dealers—with distributors and/or their buyers regularly fulfilling suspicious, voluminous orders from pharmacies and clinics, who were economically incentivized to ignore "red flags" at the point of sale before dispensing the unreasonably dangerous opioid pills.

15. Defendants' wrongful conduct has allowed millions of opioid pills to be diverted from legitimate channels of distribution to the illicit black market in quantities that have fueled the opioid epidemic affecting the Tribe. Acting against their common law and statutory duties, Defendants have created an environment in which opioid diversion is rampant. As a result, unknowing patients and unauthorized opioid users in and around the Tribe have ready access to illicit sources of diverted opioids.

16. For years Defendants and their agents have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion, but the Defendants pursued corporate revenues instead. All the Defendants in this action share responsibility for perpetuating the epidemic.

17. Defendants have foreseeably caused damages to the Tribe including the costs of providing: (a) medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) counseling and rehabilitation services; (c) treatment of infants born with opioid-related medical conditions; (d) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation; and (e) law enforcement and public safety relating to the opioid epidemic within the Tribe. The Tribe has also suffered substantial damages relating to the lost productivity of Lac Du Flambeau, as well as increased administrative costs.

18. The Tribe brings this civil action for injunctive relief, abatement of the opioids nuisance, compensatory damages, statutory damages, punitive damages, and any other relief allowed by law against the Defendant opioid drug manufacturers, distributors, and retailers that, by their actions, knowingly or negligently have manufactured, distributed and dispensed prescription opioid drugs to and within the economic proximity of the Tribe in a manner that foreseeably injured, and continues to injure, the Tribe and its members.

PARTIES

19. The Plaintiff, Lac Du Flambeau Band of Lake Superior Chippewa Indians, is a federally recognized sovereign Indian tribe with thousands of tribal members. The Tribe is governed by the organic documents and laws of the Tribe and is principally located near Lac Du Flambeau, Wisconsin. The Tribe exercises inherent sovereign governmental authority within the Tribe's Indian Lands and on behalf of the health and welfare of the Tribe and its members ("Tribal Members"), descendant children, and grandchildren and other inhabitants of the Tribe's Indian Lands. The Tribe's reservation lands are located in Vilas County, Oneida County, and Iron County, Wisconsin. Members of the Tribe are affected by the actions and conduct of the Defendants both directed at or near the Tribe's Indian Lands, as well as areas outside of the Tribe's Indian Lands. Tribal Members live both on and off the Tribe's Indian Lands.

20. A substantial number of Lac Du Flambeau tribal members have fallen victim to the opioid epidemic, becoming addicted to prescription opioids. The Tribe's foster programs are at maximum capacity with children – all of whom have been affected by opioid substance abuse. Many of these children are born addicted to opioids due to their mother's consumption of opioids during pregnancy.

21. The Tribe has incurred significant costs in an attempt to abate the opioid epidemic that continues to plague its members and Indian Lands, providing medical services and opioid-related treatments to those in need. The Tribe brings this suit, in part, to procure the financial resources required to adequately combat and abate opioid addiction, opioid-related injuries, and other problems caused by the opioid crisis.

22. This action is brought by the Tribe in the exercise of its authority as a sovereign government and on behalf of the Tribe in its proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of all Lac Du Flambeau Members as well as the non-Tribal Member inhabitants of its Indian Lands to stop the growing prescription opioid epidemic within the Tribe. The Tribe also brings this action as to recover damages and seek other redress for harm caused by Defendants' improper, wrongful, fraudulent, and tortious conduct with respect to the manufacturing, distribution, and sale of prescription opioids. Defendants' actions have caused, and continue to cause, a crisis that threatens the health, safety, and welfare of the Tribe.

23. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring actions as an enterprise and a "person," including, inter alia, standing to bring claims under the Racketeer-Influenced and Corrupt Organizations Act ("RICO"), pursuant to 18 U.S.C. § 1961(3) and 18 U.S.C. § 1964.

24. McKesson Corporation "("McKesson") is a publicly traded company headquartered in San Francisco, California and incorporated under the laws of Delaware. During all relevant times, McKesson has caused to be distributed substantial amounts of prescription opioids to providers and retailers near the Tribe and Tribal Members. McKesson has taken actions that have harmed the Tribe, Tribal Members, and the non-Tribal Member inhabitants of its Indian

Lands and it has purposefully availed itself of the advantages of conducting business within the economic proximity of the Tribe.

25. Cardinal Health, Inc. ("Cardinal") is a publicly-traded company headquartered in Ohio and incorporated under the laws of Ohio. During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers located near the Tribe. Cardinal has taken actions that have harmed the Tribe, Tribal Members, and the non-Tribal Member inhabitants of its Indian Lands and it has purposefully availed itself of the advantages of conducting business within the economic proximity of the Tribe.

26. AmerisourceBergen Corporation is a publicly-traded company headquartered in Pennsylvania and incorporated under the laws of Delaware. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers located near the Tribe. AmerisourceBergen has taken actions that have harmed the Tribe, Tribal Members, and the non-Tribal Member inhabitants of its Indian Lands and it has purposefully availed itself of the advantages of conducting business within the economic proximity of the Tribe. AmerisourceBergen Drug Corporation is a Delaware corporation and subsidiary of AmerisourceBergen Corporation with its principal place of business in Chesterbrook, Pennsylvania.

27. McKesson, Cardinal, AmerisourceBergen Corporation, and AmerisourceBergen Drug Corporation are collectively referred to hereinafter as "Distributor Defendants."

28. CVS Health is a publicly-traded Delaware corporation with its principal place of business in Rhode Island. During all relevant times, CVS Health has sold and continues to sell prescription opioids at locations near the Tribe, including in close proximity to hospitals, clinics and other health care facilities serving Tribal Members. CVS Health has taken actions that have

harmed the Tribe, Tribal Members, and the non-Tribal Member inhabitants of its Indian Lands and it has purposefully availed itself of the advantages of conducting business within the economic proximity of the Tribe.

29. Walgreens Boots Alliance, Inc., a/k/a Walgreen Co. ("Walgreens") is a publicly-traded Delaware corporation with its principal place of business in Illinois. At all relevant times, Walgreens has sold and continues to sell prescription opioids at locations near the Tribe, including those in close proximity to the hospitals, clinics, and other healthcare facilities serving the Tribe's members. Walgreens has taken actions that have harmed the Tribe, Tribal Members, and the non-Tribal Member inhabitants of its Indian Lands and it has purposefully availed itself of the advantages of conducting business within the economic proximity of the Tribe.

30. Wal-Mart Stores, Inc. ("Wal-Mart") is a publicly-traded Delaware corporation with its principal place of business in Arkansas. At all relevant times, Wal-Mart has sold and continues to sell prescription opioids at locations near the Tribe, including in close proximity to hospitals, clinics and other healthcare facilities serving the Tribe's members. Wal-Mart has taken actions that have harmed the Tribe, Tribal Members, and the non-Tribal Member inhabitants of its Indian Lands and it has purposefully availed itself of the advantages of conducting business within the economic proximity of the Tribe.

31. CVS Health, Walgreens, and Wal-Mart are collectively referred to hereinafter as the "Pharmacy Defendants."

32. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue manufactures, promotes,

sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and Wisconsin. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

33. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Wisconsin. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

34. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly- owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

35. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the U.S. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S. through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Wisconsin, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon

to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Wisconsin, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own. Through interrelated operations like these, Teva Ltd. operates in Wisconsin and the rest of the U.S. through its subsidiaries Cephalon and Teva USA. The U.S. is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as "Cephalon.")

36. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-Mcneil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc.,

and J&J hereinafter are collectively referred to as "Janssen."). Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Wisconsin, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

37. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. hereinafter are collectively referred to as "Endo.") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Wisconsin. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Wisconsin, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

38. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, later to Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc. f/k/a Watson

Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over and derives financial benefit from the marketing, sales, and profits of Allergan/Actavis products. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are referred to collectively as "Actavis.") Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Wisconsin. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

39. Mallinckrodt, PLC, an alien company doing business as Mallinckrodt Pharmaceuticals ("Mallinckrodt") with its principal place of business in the United States in St. Louis, Missouri. Mallinckrodt is one of the largest manufacturers of the generic opioid oxycodone.

40. Purdue, Cephalon, Janssen, Endo, Actavis, and Mallinckrodt are collectively referred to hereinafter as the "Pharmaceutical Defendants."

41. The Plaintiff presently lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. The Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained. The Plaintiff is informed and believes, and on such information and belief alleges, that each of the Defendants named as a

DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

JURISDICTION AND VENUE

42. This Court has subject matter jurisdiction over this action because Plaintiff brings a federal cause of action that raises federal question jurisdiction pursuant to 28 U.S.C. § 1331. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367.

43. Defendants engaged in activities and conduct that took place near, and had direct impacts on, land that constitutes Indian Lands of the Tribe.

44. The Tribe brings this action against the Defendants based on Defendants' actions that have harmed the Tribe, Tribal Members, and the non-Tribal Member inhabitants of its Indian Lands. Defendants have purposefully availed themselves of the advantages of conducting business within the economic proximity of the Tribe.

45. Defendants have substantial contacts with the the Tribe, Tribal Members, and the non-Tribal Member inhabitants of its Indian Lands.

46. Defendants have purposefully availed themselves of business opportunities within the economic proximity of the Tribe's Indian Lands.

47. Defendants' conduct has caused and is causing damages to the Tribe's proprietary and sovereign interests by imposing significant costs on the Tribe's health and welfare funding and system. In addition, Defendants' conduct has caused decreased economic productivity of Tribal Members and non-Tribal Member inhabitants of the Tribe's Indian Lands (such as Tribal member spouses and descendants) and employees of the Tribe or wholly owned enterprises of the Tribe and has harmed the long-term health and welfare of the Tribal Members and non-Tribal

Member inhabitants of the Tribe's Indian Lands (such as Tribal member spouses and descendants) and employees of the Tribe or wholly owned enterprises of the Tribe.

48. Defendants' conduct has caused and is causing a crisis within the Tribe that threatens the health, welfare, economic security and political integrity of the Tribe and all its members. Because of Defendants' actions, certain members of the Tribe have become addicted to prescription opioid drugs, causing severe injury, requiring rehabilitation and medical treatment for substance abuse disorder, causing children to be born addicted to prescription opioids and other controlled substances, and causing short and long term emotional and physical damage that requires treatment, long term care, and in some instances, foster care or adoption. The adverse financial impact on the Tribe has been enormous.

49. The negative impacts on the next generation of the Tribe's members caused by the conduct of Defendants—in particular, the ruinous effects on the health of the Tribe's children, and the removal of Tribal member children from their parents—threatens the continuation of the Tribe's culture, identity, and self-government into the future. The impacts are so severe, cumulatively, that Defendants' conduct threatens the entire Tribe.

50. This Court has personal jurisdiction over Defendants, each of which has substantial contacts and business dealings throughout Wisconsin by virtue of the distribution, dispensing, and sales of prescription opioids within Wisconsin. All causes of action herein relate to Defendants' wrongful actions, conduct, and omissions within Wisconsin and consequences and damages related to said wrongful actions, conduct, and omissions.

51. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the

interests of justice require that Plaintiff be permitted to bring all members of the nationwide RICO enterprise before the court in a single trial.

52. Venue is proper in this judicial district because many of the Defendants' acts and omissions that gave rise to the causes of action of this Complaint occurred in this judicial District.

BACKGROUND FACTS

53. Opioid means "opium like" and the term includes all drugs derived in whole or in part from the opium poppy.

54. The United States Food and Drug Administration's website describes this class of drugs as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."

55. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the Controlled Substances Act ("CSA"). They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

56. Before the epidemic of Defendants' prescription opioids, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the

serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

57. To establish and exploit the lucrative market of chronic pain patients, Defendants developed a well-funded, sophisticated, and deceptive marketing and/or distribution scheme targeted at consumers and physicians. Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use—statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including that of the Tribe.

58. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and residents of the Tribe. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the Tribe.

59. Defendants' direct and branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue ran a series of ads, called "Pain Vignettes," for OxyContin that featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old

writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in 2015-16 to stop these particularly misleading representations in New York, but continued to disseminate them in Wisconsin.

60. Defendants also promoted the use of opioids for chronic pain through "detailers" —sophisticated and specially trained sales representatives who visited individual doctors and medical staff, and fomented small-group speaker programs. In 2014, for instance, Defendants spent almost $200 million on detailing branded opioids to doctors.

61. The FDA has cited at least one Defendant for deceptive promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

62. Defendants invited doctors to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

63. Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctor, allowing specific and individual targeting, customizing, and monitoring of their marketing.

64. Defendants have had unified marketing plans and strategies from state to state, including Wisconsin. This unified approach ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.

65. Defendants deceptively marketed opioids in Wisconsin through unbranded advertising that promoted opioid use generally yet was silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by Defendants and their public relations firms and agents.

66. Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. Defendants used third-party, unbranded advertising to create the false appearance that the deceptive messages came from an independent and objective source.

67. Defendants' deceptive unbranded marketing also contradicted their branded materials reviewed by the FDA.

68. Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." Defendants paid KOLs to serve in a number of doctor-facing and public-facing

capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

69. Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG") (collectively referred to as "Front Groups").

70. Defendants collaborated, through the aforementioned organizations and groups, to spread deceptive messages about the risks and benefits of long-term opioid therapy.

71. To convince doctors and patients in Wisconsin that opioids can and should be used to treat chronic pain, Defendants had to persuade them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

72. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations—which are described below—reinforced each other and created the dangerously misleading impression that: (a) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably

were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

73. Defendants falsely claimed that the risk of opioid addiction is low, and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these false and deceptive claims by opioid manufacturers are: (a) Actavis employed a patient education brochure that falsely claimed opioid addiction is "less likely if you have never had an addiction problem;" (b) Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain*, falsely claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which falsely claimed that "[p]eople who take opioids as prescribed usually do not become addicted;" (d) Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "most people do not develop an addiction problem;" (e) Janssen distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* which described as "myth" the claim that opioids are addictive; (f) a Janssen website falsely claimed that concerns about opioid addiction are "overestimated;" (g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which falsely claims that pain is undertreated due to "misconceptions about opioid addiction".

74. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is

"extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder."

75. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013 and for other opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

76. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but there was no evidence to support that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. This agreement, however, did not extend to Wisconsin.

77. Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudo-addiction" —a term used by Dr. David Haddox, who went to work for Purdue, and Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue. Defendants falsely claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these deceptive claims are: (a) Cephalon and Purdue sponsored *Responsible Opioid Prescribing*, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated;" (c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudo-addiction by teaching that a patient's aberrant behavior was the result of untreated pain; (d) Purdue sponsored a deceptive CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse* in which a narrator notes that because of pseudo-addiction, a doctor should not assume the patient is addicted.

78. The 2016 CDC Guideline rejects the concept of pseudo-addiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

79. Pharmaceutical Defendants falsely instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very

effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Pharmaceutical Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Pharmaceutical Defendants' misrepresentations were intended to make doctors more comfortable in prescribing opioids. Some examples of these deceptive claims are: (a) an Endo supplement in the *Journal of Family Practice* emphasized the effectiveness of screening tools to avoid addictions; (b) Purdue's webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths;" (c) Purdue represented in scientific conferences that "bad apple" patients—and not opioids—were the source of the addiction crisis, when in fact the "bad apples" were the Defendants.

80. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse— "for improving outcomes related to overdose, addiction, abuse, or misuse." The Guideline emphasizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

81. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Pharmaceutical Defendants falsely claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

82. A CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, that claimed "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation", without mentioning any known or foreseeable issues.

83. Pharmaceutical Defendants deceptively minimized the significant symptoms of opioid withdrawal—which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction—and grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

84. Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences, and failed to disclose

the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example: (a) an Actavis patient brochure stated: "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction;" (b) Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain*, claiming that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain; (c) an Endo website, painknowledge.com, claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain;" (d) an Endo pamphlet *Understanding Your Pain: Taking Oral Opioid Analgesics*, stated "The dose can be increased. . . . You won't 'run out' of pain relief;" (e) a Janssen patient education guide *Finding Relief: Pain Management for Older Adults* listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages; (f) Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will; (g) Purdue's *A Policymaker's Guide to Understanding Pain & Its Management* stated that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages; (h) a Purdue CME entitled *Overview of Management Options* taught that NSAIDs and other drugs, but not opioids, were unsafe at high dosages; (i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

85. These and other representations conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

86. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

87. Pharmaceutical Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

88. Pharmaceutical Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous

abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

89. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State of New York found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies—even when they work— "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

90. These numerous, longstanding misrepresentations minimizing the risks of long-term opioid use persuaded doctors and patients to discount or ignore the true risks. Pharmaceutical Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were

supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

91. For example, Defendants falsely claimed that long-term opioid use improved patients' function and quality of life, including the following misrepresentations: (a) an Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives; (b) an Endo advertisement that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks, portraying seemingly healthy, unimpaired persons; (c) a Janssen patient education guide *Finding Relief: Pain Management for Older Adults* stated as "a fact" that "opioids may make it easier for people to live normally" such as sleeping peacefully, working, recreation, sex, walking, and climbing stairs; (d) Purdue advertisements of OxyContin entitled "Pain vignettes" implied that OxyContin improves patients' function; (e) *Responsible Opioid Prescribing*, by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function; (f) Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* counseling patients that opioids "give [pain patients] a quality of life we deserve"; (g) Endo's NIPC website *painknowledge.com* claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse"; (h) Endo CMEs titled *Persistent Pain in the Older Patient* claimed that chronic opioid therapy had been "shown to reduce pain and improve depressive symptoms and cognitive functioning"; (i) Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function"; (j) Purdue's *A Policymaker's Guide to Understanding Pain & Its Management* claimed

that "multiple clinical studies" had shown opioids as effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients; and (k) Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

92. These claims find no support in the scientific literature. The 2016 CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." The CDC reinforced this conclusion throughout its 2016 Guideline:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

93. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment

of life." In 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

94. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." The 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

95. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours— a fact that Purdue has known at all relevant times. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to

take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

96. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

97. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid- tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

98. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009.

The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain; (b) Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News, Clinical Oncology News*, and *Pain Medicine News*—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" —and not just cancer pain.

99. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain but were also approved by the FDA for such uses.

100. Purdue unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action—even where Purdue employees personally witnessed

the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

101. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

102. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

103. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including Wisconsin. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

104. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even

though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

105. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

106. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and

fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

107. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, fake independent groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

108. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions.

109. Thus, Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the Tribe now asserts. The Tribe did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

110. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

111. Defendants' deceptive marketing scheme caused and continues to cause doctors in Wisconsin to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

112. Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

113. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Wisconsin. In August 2016, the U.S. Surgeon General published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive

marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."

114. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

115. Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

116. The supply chain for prescription opioids to the consumer from the manufacture begins with the distribution of pills to the Distributor Defendants, which together account for 85-90 % of all revenues from drug distribution in the United States, an estimated $378.4 billion in 2015. The distributors then supply opioids to hospitals, pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

117. Each participant in the supply chain shares the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of

prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain, including at the pharmacy level when prescriptions are filled for any reason other than a legitimate medical purpose.

118. For example, at the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

119. Diversion occurs at the pharmacies, including whenever a pharmacist fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose or not in the usual course of practice. Some of the signs that a prescription may have been issued for an illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from different doctors (a/k/a doctor shopping), when they travel great distances between the doctor or their residence and the pharmacy to get the prescription filled, when they present multiple prescriptions for the largest dose of more than one controlled substance, or when there are other "red flags" surrounding the transaction. These signs or "red flags" should trigger closer scrutiny of the prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication for purposes to treat a legitimate medical condition. In addition to diversion via prescription, opioids are also diverted from retail outlets when stolen by employees or others.

120. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

121. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

122. Every year, millions of people in the United States misuse and abuse opioid pain relievers that can lead to addiction, overdose and death. The overdose rate among Native Americans is significantly higher than the rest of the population.

123. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged as a public health crisis in the United States. Overdose deaths involving prescription opioids are at epidemic proportions, quadrupling since 1999, concomitant with sales of these prescriptions.

124. In 2011 overdose deaths from prescription opioids reached 16,917 people. In 2014 18,893 people died from a prescription opioid related overdose. In 2015, the number of deaths increased to 22,598, even despite increased public health announcements.

125. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use. Another study revealed that 75% of those who began their opioid abuse in the 2000s started with prescription opioid. The CDC has reported that people who are dependent on prescription opioid painkillers are 40 times more likely to become

dependent on heroin. Heroin deaths are on a tragic upswing: In 2015, over 12,989 people died from heroin overdose-up more than 20% from approximately 10,574 overdose deaths in 2014.

126. The Tribe has taken proactive measures to fight against prescription opioid abuse, but such measures have not deterred Defendants' conduct.

127. Native Americans in general are more likely than other racial/ethnic groups in the United States to die from drug-induced deaths. Like other federally recognized Indian tribes, the Tribe has been hit by the effects of Defendants' opioid diversion.

128. The CDC reports that for every opioid-related death, there are on average 10 hospital admissions for abuse, 26 emergency department visits for misuse, 108 people who are dependent on opioids, and 733 non-medical users.

129. The impact on the Tribe's children has been hard. It has been reported that by 12th grade, nearly 13 percent of American Indian teens have used OxyContin, one of the most deadly opioids when misused. The use of OxyContin by American Indian 12th-graders was about double the National average.

130. A 2014 study funded by the National Institute on Drug Abuse found a much higher prevalence of drug and alcohol use in the American Indian 8th and 10th graders compared with national averages. American Indian students' annual heroin and OxyContin use was about two to three times higher than the national averages in those years.

131. The fact that American Indian teens, including the Tribe's children, are easily able to obtain OxyContin at these alarming rates indicates the degree to which opioid diversion has created an illegal secondary market for opioids.

132. It has been reported that pregnant American Indian women are up to 8.7 times more likely to be diagnosed with opioid dependency or abuse compared to the next highest

race/ethnicity; and it has been reported that in some communities upwards of 1 in 10 pregnant American Indian woman has a diagnosis of opioid dependency or abuse. On information and belief, these statistics apply similarly to pregnant women who are Tribal Members or the mothers of Tribal Members or their descendants.

133. Many of the parents of these Tribal Member children continue to relapse into prescription opioid use and lose custody of the children. As a result, many of these children are placed in foster care or adopted.

134. Defendants' opioid diversion in and around the Tribe's Indian Lands contributes to a range of social problems including physical and mental consequences, crime, delinquency, and mortality. Adverse social outcomes include child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more tribal resources are devoted to addiction-related problems, leaving a diminished pool of available resources to devote to positive societal causes like education, cultural preservation, and social programs. Meanwhile, the prescription opioid crisis diminishes the Tribe's available workforce, decreases productivity, increases poverty, and consequently requires greater government assistance expenditures by the Tribe.

135. The Tribe's community is affected by highly-addictive opioid painkillers diverted from Defendants' supply chains, thereby ensuring that the Tribal Members will continue to suffer from addiction rates higher than national averages and, commensurately, that Defendants will continue to profit by supplying opioids to the area. This civil lawsuit is the Tribe's only remaining weapon to fight against the worsening opioid abuse epidemic that Defendants have caused to the Tribe, Tribal Members, non-Tribal Member inhabitants of the Tribe's Indian Lands (such as Tribal

member spouses and descendants) and employees of the Tribe or wholly owned enterprises of the Tribe.

136. Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

137. In addition to having common law duties, the Distributor Defendants are governed by certain statutory requirements of the CSA. These requirements were enacted to protect society from the harms of drug diversion.

138. The CSA creates a legal framework for the distribution and dispensing of controlled substances, which includes requirements for registration with and reporting to the Department of Justice ("DOJ") in order to establish a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user.

139. For years the Defendants have known of the problems and consequences of opioid diversion in the supply chain.

140. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

141. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity." (emphasis added).

142. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our Country." These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

143. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have miserably and negligently failed.

144. The Distributors Defendants have knowingly or negligently allowed diversion. Their wrongful conduct and inaction have resulted in numerous civil fines and other penalties recovered by state and federal agencies- including actions by the federal Drug Enforcement Agency ("DEA") related to violations of the federal Controlled Substances Act.

145. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a U.S. Department of Justice press release announced a multi-million-dollar settlement with Cardinal for violations of the CSA. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000

doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

146. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

147. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

148. State Boards of Pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion.

149. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

150. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable danger of serious injury to the Tribe, Tribal Members, non-Tribal Member inhabitants of the Tribe's Indian Lands (such as Tribal member spouses and descendants) and employees of the Tribe or wholly owned enterprises of the Tribe.

151. The Distributor Defendants have supplied massive quantities of prescription opioids within the economic proximity of the Tribe with the actual or constructive knowledge that the opioids were ultimately being consumed by Tribal Members and non-Tribal Member inhabitants of the Tribe's Indian Lands (such as Tribal member spouses and descendants) and employees of the Tribe or wholly owned enterprises of the Tribe for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

152. Each Distributor Defendant knew or should have known that the amount of opioids that it allowed to flow into the Tribe and surrounding areas was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

153. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled

substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the Tribe's Indian Lands; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

154. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies within the economic proximity of the Tribe, servicing the Tribal Members, to perform due diligence inspections to ensure that the controlled substances the Distributors Defendants had furnished were not being diverted to illegal uses.

155. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the Tribe, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

156. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market in and around the Tribe with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

157. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death. It is also reasonably foreseeable that many of these injuries will be suffered by the

Tribe's members, and that the costs of these injuries will be borne by the Tribe.

158. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic within the Tribe, and would create access to opioids by unauthorized users, which, in tum, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

159. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed within the economic proximity of the Tribe were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third parties, and the Tribe.

160. The Distributor Defendants were aware of widespread prescription opioid abuse in and around the Tribe, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas—and in such quantities, and with such frequency—that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

161. The use of opioids by Tribal Members, non-Tribal Member inhabitants of the Tribe's Indian Lands (such as Tribal member spouses and descendants) and employees of the Tribe or wholly owned enterprises of the Tribe who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and assistance of the Distributor Defendants. If any of the Distributor Defendants adhered to effective controls to guard against diversion, significant injury could have been avoided.

162. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into the Tribe. Their participation and cooperation in a common enterprise has foreseeably caused injuries and financial damages to the Tribe, Tribal Members, non-Tribal

Member inhabitants of the Tribe's Indian Lands (such as Tribal member spouses and descendants) and employees of the Tribe or wholly owned enterprises of the Tribe. The Distributor Defendants knew full well that the Tribe would be unjustly forced to bear the costs of these injuries and damages.

163. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to a relatively small community in and around the Tribe showed an intentional or reckless disregard for the safety of the Tribe and its Tribal Members. Their conduct poses a continuing threat to the health, safety, and welfare of the Tribe.

164. Pharmacies must exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

165. Pharmacies are the "last line of defense" in keeping drugs from entering the illicit market. They are meant to be the drug experts in the healthcare delivery system and as such have considerable duties and responsibility in the oversight of patient care. They cannot blindly fill prescriptions written by a doctor.

166. The CSA imposes duties and requirements on the conduct of the Pharmacy Defendants. These requirements set a standard of care for pharmacy conduct. Under the CSA, the Pharmacy Defendants are required to maintain records and report information on Schedule II controlled substance prescriptions to the DOJ.

167. Pharmacists are required to ensure that prescriptions for controlled substances are valid and must not fill prescriptions that are not written on the required tamper-resistant forms that

are available to practitioners only from secure state-approved printers, pursuant to the CSA. Pharmacists are the last check in the opioid distribution industry. Pharmacists are to ensure that prescriptions are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

168. Pharmacy boards, national industry associations, and continuing educational programs have provided extensive guidance to pharmacists concerning their duties to the public. The guidance teaches pharmacists how to identify red flags, which indicate to the pharmacist that there may be a problem with the legitimacy of a prescription presented by a patient. The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

169. The industry guidance tells pharmacists how to recognize stolen prescription pads; prescription pads printed using a legitimate doctor' s name, but with a different call back number that is answered by an accomplice of the drug-seeker; prescriptions written using fictitious patient names and addresses, and so on.

170. Questionable or suspicious prescriptions include: prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities) for controlled substances compared to other practitioners in the area; prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; prescriptions that look "too good" or where the prescriber's handwriting is too legible; prescriptions with quantities or dosages that differ from usual medical usage; prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; photocopied prescriptions; or prescriptions containing different handwritings. Most of the time, these attributes are not difficult to detect or recognize; they should be apparent to an adequately trained pharmacist.

171. Signs that a customer is seeking opioids for the purpose of diversion include customers who: appear to be returning too frequently; are seeking to fill a prescription written for a different person; appear at the pharmacy counter simultaneously, or within a short time, all bearing similar prescriptions from the same physician; are not regular patrons or residents of the community, and show up with prescriptions from the same physician; drive long distances to have prescriptions filled; seek large volumes of controlled substances in the highest strength in each prescription; seek a combination of other drugs with opioids such as tranquilizers and muscle relaxers that can be used to create an "opioid cocktail"; and pay large amounts of cash for their prescriptions rather than using insurance. Ignoring these signs violates industry standards and DEA guidelines.

172. Other "red flags" include when prescriptions that lack the technical requirements of a valid prescription, such as a verifiable DEA number and signature; prescriptions written in excess of the amount needed for proper therapeutic purposes; prescriptions obtained through disreputable or illegal web-based pharmacies; and patients receiving multiple types of narcotic pain killers on the same day.

173. All of these issues have been presented by the DEA in pharmacist training programs throughout the United States and have been used as examples by individual state boards of pharmacy and the National Association of Boards of Pharmacy.

174. Industry standards require pharmacists to contact the prescriber for verification or clarification whenever there is a question about any aspect of a prescription order. If a pharmacist is ever in doubt, he or she must ask for proper identification. If a pharmacist believes the prescription is forged or altered, he or she should not dispense it and call the local police. If a

pharmacist believes he or she has discovered a pattern of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

175. A standard of care for the Pharmacy Defendants is also set by applicable professional regulations in Wisconsin. It is a violation of professional standards not to attempt to address the suspected addiction of a patient to a drug dispensed by the pharmacist, if there is reason to believe the patient may be addicted.

176. On information and belief, the Pharmacy Defendants regularly filled prescriptions in circumstances where red flags were present (and sometimes many red flags).

177. On information and belief, the Pharmacy Defendants regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably prudent pharmacy.

178. On information and belief, the Pharmacy Defendants have not adequately trained or supervised their employees at the point of sale to investigate or report suspicious or invalid prescriptions, or protect against corruption or theft by employees or others.

179. On information and belief, the Pharmacy Defendants utilize monetary compensation programs for certain employees that are based, in part, on the number of prescriptions filled and dispensed. This type of compensation creates economic disincentives within the companies to change their practices. For example, there have been reports of chain store supervisory personnel directing pharmacists to fill prescriptions regardless of the red flags presented.

180. The Pharmacy Defendants have violated a voluntarily undertaken duty to the public which they have assumed by their own words and actions. In news reports and other public documents, it has been reported that the Pharmacy Defendants, through their words or actions,

have assured the public that issues affecting public health and safety are the highest priority for the defendants.

181. For example, in 2015, CVS publicly stated that, "the abuse of controlled substance pain medication is a nationwide epidemic that is exacting a devastating toll upon individuals, families and communities. Pharmacists have a legal obligation under state and federal law to determine whether a controlled substance was issued for a legitimate purpose and to decline to fill prescriptions they have reason to believe were issued for a non-legitimate purpose."

182. In failing to take adequate measures to prevent substantial opioid-related injuries to the Tribe and its members, the Pharmacy Defendants have breached their duties under the "reasonable care" standard, professional duties under the relevant standards of professional practice, and requirements established by Wisconsin law.

183. It is foreseeable to the Pharmacy Defendants that filling invalid or suspicious prescriptions for opioids would cause harm to individual pharmacy customers, including Tribal Members who may use the wrongfully dispensed opioids, and would also the Tribal government.

184. It is reasonably foreseeable to the Pharmacy Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including overdoses and death. It is also reasonably foreseeable many of these injuries will be suffered by the Tribe and its Tribal Members.

185. At all relevant times, the Pharmacy Defendants have engaged in improper dispensing practices, and continue to do so, despite knowing full well they could take measures to substantially eliminate their complicity in opioid diversion.

186. At all relevant times, the Pharmacy Defendants engaged in these activities, and continue to do so, knowing full well that the Tribe, in its role of providing protection and care for

its members, would provide or pay for additional medical services, emergency services, law enforcement, and other necessary services, as well as by the loss of substantial economic productivity that contributes to the health and well-being of the Tribe.

187. It is reasonably foreseeable to the Pharmacy Defendants that the Tribe would be forced to bear substantial expenses as a result of the Pharmacy Defendants' acts.

188. The Pharmacy Defendants were on notice of their ongoing negligence or intentional misconduct towards the Tribe in part because of their history of being penalized for violating their duties and legal requirements in other jurisdictions.

189. In 2013, Defendant CVS agreed to pay $11 million to avoid civil charges for violating federal laws relating to the sales of prescription opioids at pharmacies in the State of Oklahoma. Specifically, CVS allegedly violated the recordkeeping requirements for tracking and dispensing prescription drugs including oxycodone and hydrocodone.

190. Defendants CVS, Walgreens, and Wal-Mart each have one or more pharmacies ranked in the top ten pharmacies that fill prescriptions for opioids, some of which are operating in an area where Tribal Members fill their prescriptions. All have been prosecuted and disciplined for diversion of prescription opioids.

191. The Pharmacy Defendants were also aware of the magnitude of the opioid diversion crisis based on investigations into their practices elsewhere. For example, in 2013, Walgreens settled with the DEA for $80 million, resolving allegations that it committed an unprecedented number of record-keeping and dispensing violations at various retail locations and a distribution center. As part of the settlement, Walgreens agreed to enhance its training and compliance programs, and to no longer compensate its pharmacists based on the volume of prescriptions filled.

192. CVS also agreed to pay $450,000 to resolve allegations that pharmacists were

filling opioid prescriptions written by unauthorized medical personnel. More recently, in 2016, CVS settled a case pending in Massachusetts, by agreeing to pay $3.5 million to resolve allegations that 50 CVS stores violated the federal CSA by filling forged oxycodone prescriptions more than 500 times between 2011 and 2014.

COUNT I

RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1961 et seq.

193. The Tribe re-alleges and incorporates by reference the foregoing paragraphs.

194. Defendants conducted and continue to conduct their business through illegitimate means in an association-in-fact enterprise and/or legal entity enterprise.

195. Defendants are persons under 18 U.S.C. § 1961(3) because they are entities holding a legal or beneficial interest in property.

196. Defendants have aggressively sought to increase and generate profits from the prescription opioid market by unlawfully increasing the volume of opioids manufactured, distributed, and sold.

197. As registrants under the CSA, Defendants are not permitted to limitlessly expand the opioid market through unlawful sales of regulated prescription opioids.

198. The CSA restricts and regulates Defendants' ability to manufacture and distribute prescription opioids, requiring Defendants to maintain effective preventative measures against opioid diversion, including, but not limited to: monitoring and identifying suspicious orders, preventing suspicious order from being filled, reporting suspicious orders to the DEA, and to not exceed sales quotas established by the DEA.

199. These precautionary methods created by the CSA were intentionally established to reduce or eliminate the potential for opioid diversion.

200. The Defendants found it impossible to maximize profits within the legal framework of the CSA. Choosing illegal profits over the law, Defendants systematically and fraudulently violated their statutory duties of maintaining effect anti-diversion measures through the intentional failure to report suspicious orders and the repeated unlawful sales of prescription opioids. As a result, Defendants illegally increased the annual production quotas for prescription opioids.

201. The term "enterprise" is defined as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). The definition of "enterprise" in § 1961(4) includes both legitimate and illegitimate enterprises.

202. Pharmaceutical Defendants and Distributor Defendants forged an association-in-fact enterprise to perpetrate their illegal scheme of illegally increasing the production of prescription opioids (collectively referred to as the "Opioid Diversion Enterprise"). In concert and through the Opioid Diversion Enterprise, Defendants participated in an illegal scheme, the purpose of which was to engage in the unlawful sale of prescription opioids while deceiving the public and regulators into believing that Defendants were faithfully complying with their statutory obligations. The Opioid Diversion Enterprise enabled Defendants to profit billions of dollars in the unlawful sale of opioids. As a direct result of Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, Defendants were able to extract billions of dollars in profit from millions of addicted Americans and Tribe members, while entities such as the Tribe experienced tens of millions of dollars in damages caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

203. Defendants formed an additional association-in-fact enterprise to unlawfully market the safety and efficacy of prescription opioids (collectively referred to as the "Opioids Promotion Enterprise"). The Opioids Promotion Enterprise is comprised of Defendants, including their employees and agents; Front Groups, including their employees and agents; and KOLs; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioids Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendants to fraudulently market opioids as scientifically proven as safe and effective.

204. The Opioids Promotion Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioids Promotion Enterprise was created and organized to effectuate a pattern of racketeering activity, and maintained systematic links for a common purpose: to ensure the continued prescription of opioids for chronic pain. Each of these entities, including the Defendants, is a "person" distinct from the Opioids Promotion Enterprise.

205. The Opioids Promotion Enterprise and Opioids Diversion Enterprise scheme empowered Defendants to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent schemes, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while Plaintiff suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

206. Members of the Opioid Diversion Enterprise systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of

suspicious orders, and to notify the DEA of suspicious orders. As alleged herein, through the Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

207. Alternatively, Defendants were also members of a legal entity enterprise. The Healthcare Distribution Alliance ("HDA") is a distinct legal entity that qualifies as an enterprise under 18 U.S.C. § 1961(4). The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia.

208. The Defendants utilized the HDA to conduct a RICO enterprise and to engage in the pattern of racketeering activity that gives rise to the RICO Count.

209. Each of the Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the Defendants.

210. Therefore, the HDA exists separately from the Opioid Diversion Enterprise and the Opioid Promotion Enterprise, and each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

211. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid Diversion Enterprise) and the HDA were each used by the Defendants to engage in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are collectively referred to as the "RICO Enterprise."

212. It is unlawful for a CSA registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

213. At all relevant times, the Defendants operated as an enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

214. At all relevant times, the RICO Enterprise: (a) existed separately and distinctly from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astonishing growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

215. The RICO Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion.

216. Members of the HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke

registrations. The HDA contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties.

217. The RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the United States and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same

218. The Defendants colluded to ensure that the quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Pharmaceutical Defendants in their lobbying efforts through the HDA;

b. The Distributor Defendants invited the participation, oversight and control of the Pharmaceutical Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. The Distributor Defendants provided sales information to the Pharmaceutical Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Pharmaceutical Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

f. The Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

g. The Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders;

h. The Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA;

i. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

219. Defendants took intentional and affirmative steps to conceal the RICO scheme through the use of unbranded advertisements, third parties, and the Front Groups to disguise the source of the Defendants' fraudulent statements.

220. The pattern of racketeering activity: Each time a participant in the illegal RICO scheme distributed a false statement by mail or wire, it committed a separate act of mail fraud or wire fraud under federal law.

221. Defendants used and caused to be used thousands of interstate mail and wire communications through uniform misrepresentations, concealments, and material omissions regarding the safety and efficacy of opioids and their compliance with the CSA's anti-diversion statutes. The Defendants committed this pattern of racketeering activity on a continual and regular basis with the intent to advance the illegal scheme of the Rico Enterprise.

222. Defendants also engaged in a pattern of racketeering activity in the unlawful manufacture, distribution, and sale of prescription opioids, a controlled substance under the CSA. Defendants routinely and intentionally furnished false, misleading, or incomplete information in their reports to the DEA and in their applications for production quotas.

223. Plaintiff has injuries that were directly caused by the Defendants' racketeering activities.

224. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms that are unique to the Tribe and its members.

225. Plaintiff seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT II

VIOLATION OF THE WISCONSIN UNFAIR AND DECEPTIVE PRACTICES ACT

226. The Tribe re-alleges and incorporates by reference the foregoing paragraphs.

227. The Wisconsin Deceptive and Unfair Trade Practices Act ("WDTPA"), Wis. Stat. § 100.18, prohibits deceptive acts or practices in the conduct of any trade or commerce. Defendants, individually, jointly, and severally, made representations to the public with the intent

to induce an obligation; the representations were untrue, deceptive, and/or misleading; and, the representations materially induced and/or caused pecuniary loss to the Plaintiff, Lac Du Flambeau.

228. Defendants were in the position to implement effective business practices to guard against diversion of the highly addictive opioid products they sell and distribute. Instead, they profited off the prescription drug epidemic plaguing Lac Du Flambeau by ignoring anti-diversion laws, while burdening the Lac Du Flambeau with the externalities created by their conduct.

229. Defendants turned a blind eye to the problem of opioid diversion and profited from the sale of prescription opioids to the members of the Lac Du Flambeau in quantities that far exceeded the number of prescriptions that could reasonably have been used for legitimate medical purposes, despite having notice or actual knowledge of widespread opioid diversion from prescribing records, pharmacy orders, field reports, and sales representatives.

230. The foregoing conduct constitutes an unfair, deceptive, unscrupulous, and immoral trade practice that is against public policy, in violation of WDTPA.

231. Certain wrongful acts categorically violate WDTPA.

232. Each act by any Defendant that violated the WDTPA by: filling suspicious or invalid orders for prescription opioids at both the wholesale and retail level; failing to maintain effective controls against opioid diversion; failing to operate an effective system to disclose suspicious orders of controlled substances; failing to report suspicious orders of controlled substances; failing to reasonably maintain necessary records of opioid transactions; and, deliberately ignoring questionable and/or obviously invalid prescriptions and filling them anyway.

233. The aforementioned actions and conduct of Defendants constitute violations of the WDTPA and each caused substantial damage and injury to the Lac Du Flambeau or the members of the Lac Du Flambeau.

234. The Lac Du Flambeau is entitled to recover civil penalties for each of Defendants' violations, as well as injunctive relief, reasonable attorneys' fees, and whatever other relief may be deemed appropriate.

COUNT III

NUISANCE

235. The Tribe re-alleges and incorporates by reference the foregoing paragraphs.

236. The nuisance is the over-saturation of opioids within the economic proximity of the Tribe, and to Tribal Members, for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

237. All Defendants substantially participated in nuisance-causing activities.

238. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids from premises around the Tribe to unintended users in the Tribe—including children, people at risk of overdose or suicide, and criminals.

239. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

240. Defendants' activities unreasonably interfere with the following common rights of the Tribal Members:

a. To be free from reasonable apprehension of danger to person and property;

b. To be free from the spread of disease within the community including the disease of addiction and other diseases associated with widespread illegal opioid use;

c. To be free from the negative health and safety effects of widespread illegal drug sales on premises in and around the Tribe;

d. To be free from blights on the community created by areas of illegal drug us

e. The right to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and to foster a secondary market of illegal transactions; and

f. The right to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

241. The Defendants' interference with these rights of the Tribe is unreasonable because it:

a. Has harmed and will continue to harm the public health and public peace of the Tribe;

b. Has harmed and will continue to harm the Tribe's community by increasing the levels of vagrancy, and property crime, and thereby interfering with the rights of the Tribal community at large;

c. Is of a continuing nature, and it has produced a long-lasting effect; and

d. Defendants have reason to know their conduct has a significant effect upon the public rights of the Tribe and its Tribal Members.

242. The nuisance undermines Tribal Members' public health, quality of life, and safety. It has resulted in increased crime and property damage within the Tribe. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within the Tribe's families and its entire community, which threatens the fabric of the Tribe and its general welfare.

243. Public resources are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources that could be used to benefit the Tribe at large.

244. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions.

245. At all times, all Defendants possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacy locations or other points of sale into the surrounding Tribal community. Distributor Defendants had the power to shut off the supply of illicit opioids into the Tribe.

246. As a direct and proximate result of the nuisance, Tribal Members, non-Tribal Member inhabitants of the Tribe's Indian Lands (such as Tribal member spouses and descendants), employees of the Tribe or wholly owned enterprises of the Tribe and people who come into the Tribe's Indian Lands have suffered in their ability to enjoy rights of the public.

247. As a direct and proximate result of the nuisance, the Tribe has sustained economic harm by spending a substantial amount of money trying to fix the societal harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, healthcare, child services and law enforcement.

248. The Tribe has also suffered unique harms of a kind that is different from the Tribal Members at large, namely, that the Tribe has been harmed in its proprietary interests.

249. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

250. Defendants should be required to abate the nuisance and/or pay the expenses the Tribe has incurred or will incur in the future to fully abate the nuisance, and punitive damages.

COUNT IV

NEGLIGENCE AND GROSS NEGLIGENCE

251. The Tribe re-alleges and incorporates by reference the foregoing paragraphs.

252. Defendants owe a non-delegable duty to the Tribe to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

253. There is no social value to Defendants' challenged behavior. In fact, Defendants' behavior is against the law, i.e., facilitating the diversion of opioids to the illicit black market.

254. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of the Tribe and its members.

255. There is an extremely high likelihood of Defendants' behavior causing a substantial injury to the Tribe's interests. The harmful consequences of opioid diversion are apparent from the statistics related to prescription opioid overdoses and deaths.

256. Defendants' conduct fell below the reasonable standard of care. Their negligent acts include:

a. Consciously oversupplying the market in and around the Tribe with highly-addictive prescription opioids,

b. Using unsafe distribution and dispensing practices;

c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

d. Inviting criminal activity into the Tribe by disregarding precautionary measures built into the CSA, pharmacy board regulations, and applicable law;

e. Failing to properly train or investigate their employees;

f. Failing to properly review prescription orders for red flags;

g. Failing to report suspicious orders or refuse to fill them;

h. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances; and

i. Failing to police the integrity of their supply chains.

257. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

258. Each Defendant sold prescription opioids in the supply chain knowing both that (1) there was a substantial likelihood many of the sales were for non-medical purposes, and (2) opioids are an inherently dangerous product when used for non-medical purposes.

259. Defendants were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

260. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

261. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, e.g., the foreseeable conduct of: corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

262. Defendants are in a limited class of registrants authorized to legally distribute controlled substances to, among, and within the economic proximity of the Tribe. This places Defendants in a position of great trust and responsibility vis-a-vis the Tribe. Defendants owe a special duty to the Tribe; the duty owed cannot be delegated to another party.

263. The Tribe is without fault, and the injuries to the Tribe and its members would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

264. The aforementioned conduct of Defendants proximately caused damage to the Tribe including increased healthcare and law enforcement costs, lower tax revenue, and lost productivity.

COUNT V

UNJUST ENRICHMENT

265. The Tribe re-alleges and incorporates by reference the foregoing paragraphs.

266. The Tribe has expended substantial amounts of money to fix or mitigate the societal harms caused by Defendants' conduct.

267. The expenditures by the Tribe in providing healthcare services to people who use opioids have added to Defendants' wealth. The expenditures by the Tribe have helped sustain Defendants' businesses.

268. The Tribe has conferred a benefit upon Defendants, by paying for what may be called Defendants' externalities-the costs of the harm caused by Defendants' negligent distribution and sales practices.

269. Defendants are aware of this obvious benefit, and that retention of this benefit is unjust.

270. Defendants made substantial profits while fueling the prescription drug epidemic in the Tribe's community.

271. Defendants continue to receive considerable profits from the distribution of controlled substances in the Tribe's Indian Lands.

272. Defendants have been unjustly enriched by their negligent, intentional, malicious, oppressive, illegal and unethical acts, omissions, and wrongdoing.

273. It would be inequitable to allow Defendants to retain benefit or financial advantage.

274. The Tribe demands judgment against each Defendant for restitution, disgorgement, and any other relief allowed in law or equity.

COUNT VI

AS TO PHARMACEUTICAL DEFENDANTS
COMMON LAW FRAUD

275. The Tribe re-alleges and incorporates by reference the foregoing paragraphs.

276. Pharmaceutical Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

277. Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following: (a) advertising that opioids improved long-term functioning long-term and were suitable for the treatment of chronic non-cancer pain; (b) promoting the concept of

pseudo-addiction; (c) brochures concerning indicators of possible opioid abuse; (d) suitability of opioids for high-risk patients; (e) publications presenting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (f) concealment of funding of pro-opioid KOL doctors regarding treatment for chronic non-cancer pain; (g) downplaying of the risks of opioid addiction; (h) CMEs promoting the use of opioids to treat chronic non-cancer pain; (i) promotion of misleading scientific studies regarding the safety and efficacy of opioids for long-term treatment of chronic non-cancer pain; (j) misuse and promotion of data to mask the true safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including rates of abuse and addiction and the lack of validation for long-term efficacy; (k) misleading statements in education materials for Wisconsin hospital doctors and staff under guise of educating them on new pain standards; (l) in-person detailing; and (m) withholding from Wisconsin law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs.

278. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following: (a) false patient education materials; (b) advertising the ability of opioids to improve function long-term and the efficacy of opioids long-term for the treatment of chronic non-cancer pain; (c) promoting chronic opioid therapy as safe and effective for long term use for high- risk patients; (d) Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse; (e) concealing the true risk of addiction and promoting the misleading concept of pseudo-addiction; (f) promoting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (g) secretly funding pro-opioid KOLs, who made deceptive

statements concerning the use of opioids to treat chronic non-cancer pain; (h) funding pro-opioid pain organizations responsible for egregious misrepresentations concerning the use of opioids to treat chronic non-cancer pain; (i) downplaying the risks of opioid addiction in the elderly; (j) CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (k) misleading scientific studies concluding opioids are safe and effective for the long-term treatment of chronic non-cancer pain and quality of life, while concealing contrary data; (l) funding and promoting pro-opioid KOLs concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction; (m) manipulation of data regarding safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and (n) in-person detailing.

279. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following: (a) patient education materials containing deceptive statements regarding the suitability, benefits, and efficacy of opioids; (b) stating that opioids were safe and effective for the long-term treatment of chronic non-cancer pain; (c) stating that opioids improve quality of life, while concealing contrary data; (d) concealing the true risk of addiction; (e) promoting the deceptive concept of pseudo-addiction; (f) promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious, and concealing this information; (g) presenting to the public and doctors an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (h) funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (i) funding pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer

pain; (j) using CMEs to promote false statements concerning the use of opioids to treat chronic non-cancer pain; and (k) in-person detailing.

280. Defendant Cephalon made and/or disseminated untrue, false, and deceptive statements minimizing the risk of addiction of opioids, promoting the concept of pseudo-addiction, advocating the use of opioids for chronic non-cancer pain, funding misleading CMEs, KOL doctors, and pain organizations, minimizing the addictiveness of Cephalon's potent rapid-onset opioids, and promoting the suitability of Cephalon's rapid-onset opioids to general practitioners, neurologists, sports medicine specialists, and workers' compensation programs.

281. Defendants Actavis and Mallinckrodt made and/or disseminated deceptive statements, including, but not limited to, the following: (a) promotion of use of opioids to treat chronic non-cancer pain to Wisconsin prescribers through in-person detailing; (b) advertising that opioids were safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improved quality of life; (c) advertising that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain.

282. These false representations and concealments were reasonably calculated to deceive prescribing physicians in the patient areas of the Tribe, were made with the intent to deceive, and did in fact deceive physicians who prescribed opioids for chronic pain.

283. But for these false representations and concealments of material fact, the Tribe would not have incurred excessive costs and economic loss.

284. As a direct and proximate cause of Defendants' fraudulent conduct, the Tribe has suffered damages.

COUNT VII

CIVIL CONSPIRACY

285. The Tribe re-alleges and incorporates by reference the foregoing paragraphs.

286. The Distributor Defendants continuously supplied prescription opioids to the Pharmacy Defendants despite having actual or constructive knowledge that said pharmacies were habitually breaching their common law duties.

287. Without the Distributor Defendants' supply of prescription opioids, the Pharmacy Defendants would not be able to fill and dispense the increasing number of prescription opioids throughout the Tribe's Indian Lands.

288. The Pharmacy Defendants continuously paid the Distributor Defendants to supply large quantities of prescription opioids in order to satisfy the demand for the drugs.

289. Neither side would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party.

290. As a result of the concerted action between the Distributor Defendants and the Pharmacy Defendants, the Tribe and its members have suffered damage.

291. The Tribe demands judgment against each Defendant for compensatory and punitive damages.

COUNT VIII

VIOLATION OF WISCONSIN'S FRAUDULENT DRUG ADVERTISING ACT

292. The tribe re-alleges and incorporates by reference the foregoing paragraphs.

293. Wisconsin's Fraudulent Drug Advertising Act, Wis. Stat. § 100.182, prohibits deceptive acts or practices in the marketing and advertising of drugs.

294. Defendants, individually, jointly, and severally, made representations with respect to the efficacy and safety of prescription opioids to the public; the representations were untrue, deceptive, and/or misleading; and, the representations materially induced and/or caused pecuniary loss to the Plaintiff, Lac Du Flambeau.

295. Defendants implemented a series of misleading advertisements, falsely promoting the efficacy of prescription opioids for the treatment of chronic pain.

296. Defendants implemented a series of misleading advertisements, deceptively diminishing and concealing the risks of opioid addiction and the safety of using opioids to improve quality of life.

297. The aforementioned actions and conduct of Defendants constitute violations of the Wisconsin's Fraudulent Drug Advertising Act, and each caused substantial damage and injury to the Lac Du Flambeau and its members.

PRAYER FOR RELIEF

Wherefore, premises considered, the Lac Du Flambeau Band of Lake Superior Chippewa Indians prays that the Court grant the following relief against all Defendants, individually, jointly, and severally as follows:

(a) Injunctive Relief as against the Defendants for their wrongful, tortious, and illegal activities as alleged hereinabove;

(b) Compensatory, consequential, and incidental damages;

(c) All available equitable remedies, including restitution and disgorgement of revenue and profits;

(d) Punitive damages;

(e) Attorneys' fees and all costs and expenses related to this civil action; and

(f) All such other relief this Court and/or jury deems just and fair;

(g) Trial by jury for all counts so triable.

Dated: March 30, 2018

Respectfully Submitted,

PLAINTIFF LAC DU FLAMBEAU BAND OF LAKE SUPERIOR CHIPPEWA INDIANS,

/s/ Andrew Adams III

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